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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,774	12/21/2000	Christine A. Klein	50370-60637CDV	5116
21874	7590	06/14/2005	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			CHANDRA, GYAN	
			ART UNIT	PAPER NUMBER

1646

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/747,774	KLEIN ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,8,17,25-27,36,37,39,50,51,53,77 and 78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,8,17,25-27,36,37,39,50,51,53,77 and 78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/11/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

PD

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Claims 77-78 have been added. Claims 1, 2, 5, 8-1 1, 17, 25-27, 36, 37, 39, 50, 51, 53, 77 and 78 are pending and under consideration.

The text of those sections of Title 35, U.S. code not included in this action can be found in a prior Office Action.

Response to Arguments

Claim Rejections - 35 USC § 101 and 35 USC § 112, First Paragraph

The rejection of claims 1, 2, 5, 8-1 1, 17, 25-27, 36, 37, 39, 50, 51, 53, 77 and 78 under 35 USC § 101 is maintained for the reasons of record. Applicant's arguments filed, see Remarks, on 4/11/2005 have been fully considered but they are not persuasive. The claimed invention is drawn to a mixture of recombinant yeast cells comprising a recombinant heterologous orphan G protein coupled receptor, wherein the receptor is expressed on the cell membrane and a recombinant gene encoding a heterologous test peptide, wherein the test peptide is transported to a location allowing interaction with the receptor expressed on the cell membrane.

Applicant argues that the G protein coupled receptors are structurally and functionally related proteins characterized by seven membrane-spanning receptors and play important roles in biology through a similar signaling pathway. Applicant's claim is directed to a mixture of recombinant cells comprising a recombinant heterologous orphan G protein coupled receptor. It is known in the art that there are more than a

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thousand GPCRs are present in humans and they play important biological functions but an orphan GPCR by definition does not have a known ligand and its biological function is yet to be established. The instant invention lacks a specific and substantial real world utility absent elucidation of the biological function of the orphan receptor and any role that the ligands identified as modulators of the receptor would play in modulation or identification of any disease state associated with that biological function. Without further research and experimentation, the claimed yeast cells do not provide an immediate benefit to the public. The biological research contemplated using applicants' yeast cells is to take place sometime in the future, only after elucidation of the biological role of the orphan receptor. Applicant argues that "orphan receptors" are conserved in evolution and are distributed through out the body like other known receptors and therefore, are involved in human biological function. There are hundreds, if not thousands, of orphan GPCRs expressed through out in the body, and merely stating that they should have a biological function, dose not establish a real world use because in order to establish their biological role to a disease association or a pathophysiology, significant experimentation would be required. Applicant cites examples of genetic linkage of mutations in genes (GPCRs) with a disease association. This shows that GPCR play important roles in biology. But this does not establish a real world use of the claimed invention directed to a mixture of recombinant cells comprising a recombinant heterologous orphan G protein coupled receptor.

Applicant further argues that the claimed invention has utility in screening assays for identifying a ligand that would modify yeast signal transduction activity. As is

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specifically set forth in the utility guidelines, however, research tools are useful only where they can be used in conjunction with other method steps to evaluate materials other than themselves or to arrive at some result. The claimed yeast cells comprising a gene encoding an orphan G protein coupled receptor are not research tools in this sense. Rather, they are themselves the subject of basic research. The usefulness or lack thereof of the subject of basic orphan G protein coupled receptor is yet to be established. In the absence of any data as to the receptor's biological function, there is no basis upon which to base a specific or substantial utility for the claimed yeast cells comprising a gene encoding the receptor. The instant invention of recombinant yeast cells comprising a recombinant orphan G protein coupled receptor and a recombinant heterologous polypeptide is a basic research tool to identify a possible peptide ligand that binds to a receptor, and is not a direct mean of associating an orphan G protein coupled receptor to a relevant biological function of the receptor. Significant experimentation would be required to elucidate biological function of orphan receptor. Basic research using orphan receptors to study themselves does not meet the standard for utility.

The rejection of claims 1, 2, 5, 8-11, 17, 25-27, 36, 37, 39, 50, 51, 53, 77 and 78 under 35 USC § 112, first paragraph, as lacking enablement, is maintained.

Claim Rejections - 35 USC § 103

Applicant's arguments, see Remarks, filed 4/11/2005, with respect to the rejection under 35 USC 103(a) have been fully considered and are persuasive. The rejection of claims 1, 2, 5, 8-11, 17, 25-27, 36, 37, 39, 50, 51, 53, 77 and 78 under 35 USC 103(a) has been withdrawn.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra
AU 1646
8 June 2005


JANET ANDRES
PRIMARY EXAMINER